In Re: Boatman et al.
Serial No.: 09/848,742
Date Filed: May 3, 2001

PCT

WORLD INTELLECTUAL PROPERTY ORGANIZATION
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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61M 29/00	A1	(11) International Publication Number: WO 97/25093 (43) International Publication Date: 17 July 1997 (17.07.97)

(21) International Application Number: PCT/US96/20302

(22) International Filing Date: 20 December 1996 (20.12.96)

(30) Priority Data:
08/582,722 4 January 1996 (04.01.96) US

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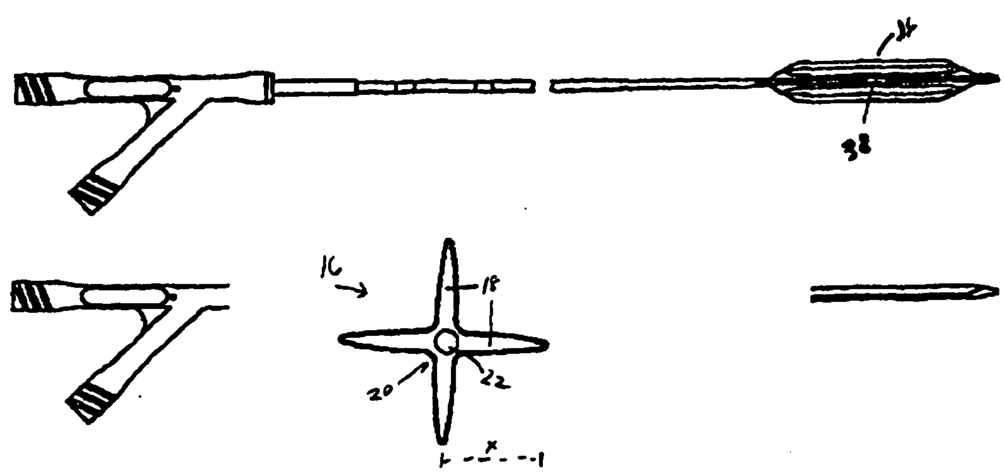
(81) Designated States: AU, CA, JP, European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published
With international search report.

(54) Title: FLUTED BALLOON CATHETER



(57) Abstract

The present invention provides a catheter (10) with at least one lumen (22) therethrough, and a balloon (16) sealingly engaged in fluid communication with the lumen (22). The balloon (16) has a predetermined folding pattern with at least three collapsible grooves or depressions (20). Upon deflation, the grooves or depressions (20) automatically collapse inward, resulting in a folded configuration which can be twisted into a very low profile configuration. The catheter body (10) preferably is made of polyether ether ketone ("PEEK"), and the fluted balloon (16) preferably is made of polyvinylidine fluoride ("PVDF") and polyurethane.

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TITLE: FLUTED BALLOON CATHETER

INVENTOR: BANDULA WIJAY

Field of the Invention

The present invention relates generally to the field of surgery, and particularly to instruments for facilitating the performance of surgery related to the flow of blood. More particularly, the invention relates to balloon catheters that have a predetermined folding pattern for ease in removing or relocating the balloon after insertion into a blood vessel. Upon deflation, the balloons collapse according to the predetermined folding pattern to result in a low profile configuration.

Background of the Invention

When a patient is afflicted with an obstructed coronary artery, the artery typically is dilated using a procedure known as percutaneous transluminal coronary angioplasty ("PTCA"). PTCA is performed using a "balloon" catheter (or a PTCA catheter). A balloon catheter consists, very basically, of an inflatable balloon and a means for guiding the balloon to the target occlusion and for inflating the balloon to dilate the artery at the point of the occlusion. Preferably, the catheter also permits simultaneous monitoring of aortic pressure and/or simultaneous dye injections to clarify the vascular anatomy.

Once it is determined that PTCA is called for, a guiding catheter typically is introduced through a sheath which guides

the catheter to the aortic origin of the vessel to be dilated. Once the guidewire reaches the lesion, the guiding catheter supports the balloon catheter as it is threaded onto the guidewire until the "balloon" portion of the catheter reaches the occlusion. The balloon portion then is inflated from an external port, resulting in compression of the atheromatous lesion in a manner perpendicular to the vessel, thus dilating the lumen.

Clinical experience has revealed that a balloon catheter system having the lowest profile is desirable in order to facilitate the passage of the balloon across severe and remote vascular obstructions. Known angioplasty catheters have been shipped to doctors and hospitals in sterilized condition with the balloon deflated and in a "wing-folded" condition. Essentially, wing folding involves flattening of the balloon along the catheter body and folding the balloon over onto the catheter body in two segments which resemble wings coming from a fuselage. In the past, the catheters were wing-folded in the factory prior to shipment.

One problem encountered with wing-folded balloons was that the doctor and/or technician generally had to inject a contrast fluid to displace gas in the balloon. As a result, the balloon lost its low profile, "wing-folded" configuration. In order to avoid the need to displace gas in the balloon, manufacturers could prefill the balloon with contrast fluid and place a sleeve over the balloon to maintain the low profile, wing-folded position.

Although "wing-folded" balloons have a low profile during insertion, the balloons unfold upon inflation. After the target blood vessel is dilated, the balloon must again be returned to a low profile for ease in removing the catheter and/or repositioning to dilate a different blood vessel. Unfortunately, it is difficult to manipulate a deflated balloon positioned inside of a blood vessel to achieve a low profile configuration. A balloon having a construction that would automatically return to a low profile configuration upon deflation would be very advantageous.

Summary of the Invention

The present invention provides a catheter with at least one lumen therethrough and a balloon sealingly engaged in fluid communication with the lumen. The balloon has a predetermined folding pattern with at least three collapsible grooves or depressions. Upon deflation, the grooves or depressions automatically collapse inward, resulting in a folded configuration which can be twisted into a very low profile configuration. The catheter body preferably is made of polyetheretherketone ("PEEK"), and the fluted balloon preferably is made of polyvinylidine fluoride ("PVDF"), polyurethane, and polyester terephthalate.

Brief Description of the Drawings

Fig. 1 is a schematic diagram of a balloon angioplasty catheter according to the present invention wherein the balloon is inflated.

Fig. 2 is a schematic diagram of a balloon angioplasty catheter according to the present invention wherein the balloon is deflated.

Fig. 3 is a schematic diagram of a balloon angioplasty catheter according to the present invention wherein the balloon is deflated and has been folded in on itself.

Fig. 4 is a blow up of the balloon depicted in Fig. 1 indicating a cross section at line B-B.

Fig. 4A is a schematic cross section along line B-B in Fig. 4.

Fig. 4B is a schematic cross section of the section in Fig. 4A when the balloon unfolded.

Fig. 5 is a blow up of the balloon portion of the catheter in Fig. 2 indicating a cross section at line A-A.

Fig. 5A is a cross section along line A-A in Fig. 5 when the balloon has one predetermined folding pattern.

Fig. 5B is a cross section along line B-B in Fig. 5 when the balloon has another predetermined folding pattern.

Fig. 6A is a side view of a balloon catheter having a necked down catheter body, a necked down perfusion lumen, and an inner strengthening wire.

Fig. 6B is a blowup of the necked down region of the catheter shown in Fig. 6A, with the internal lumens and wire depicted as dotted lines.

Fig. 6C is a cross section along line C-C in Fig. 6B.

Fig. 7A is a side view of a balloon catheter having a necked down catheter body, a perfusion lumen that is not necked down, and an inner strengthening wire.

Fig. 7B is a blowup of the necked down region of the catheter shown in Fig. 7A, with the internal lumens and wire shown as dotted lines.

Fig. 7C is a cross section along line D-D in Fig. 7B.

Fig. 8 is a schematic diagram of a typical balloon with no predetermined folding pattern which has been "wing folded."

Fig. 9 is a schematic of a cross section through an inflated balloon.

Fig. 10 is a schematic of a typical balloon with no predetermined folding pattern after deflation.

Detailed Description of the Invention

Fig. 1 depicts a balloon catheter system 10 which includes a proximal section 12 secured proximally to a fitting 14. Many suitable fittings 14 are known in the art. The particular fitting that is used with the catheter is not critical to the invention; however, the fitting must have certain features in order to be compatible with the catheter. The fitting 14 must include a mechanism 13 for inserting and maneuvering a guidewire (not shown) and also for pumping perfused blood, drugs, and/or dyes, preferably through another lumen (22 in Figs. 4-7) in the proximal section 12 and out the distal portion of the catheter 10. The fitting 14 also should have a mechanism 15 to inflate the balloon.

The fitting 14 preferably should be insert-molded using known methods to process high-density polyethylene. At the distal end of the catheter 10 is a balloon 16. In a preferred embodiment, the balloon is made of polyvinylidine fluoride ("PVDF"), preferably KYANAR™ (a product available from Pennwalt Corporation), polyurethane, polyester terephthalate, or blends thereof. These plastics are available from numerous sources, such as Pennwalt Corporation. Various blends of these materials may be used to alter the properties of the balloon. A preferred blend of materials for the balloon is 40 wt% KYANAR™, 5 wt% polyurethane, and 44 wt% polyester terephthalate.

A balloon made of a polymeric mix containing PVDF is preferred because such balloons are strong, can be biaxially oriented, and have good memory characteristics. The balloon also can be made of other suitable materials, including but not limited to, polyethylene, polyurethane, or polyester. Polyethylene and polyurethane balloons tend to have thick walls which withstand high pressures and distend considerably in response to internal pressure. Polyester balloons and balloons made of a blend containing PVDF, have significantly thinner walls but nevertheless will withstand high pressures and distend only minimally with increased internal pressure. The balloon may be made in a variety of sizes between about 1.5-10.0 mm using known procedures.

In the typical balloon catheter, the balloon 16 is molded to have a smooth, flexible surface with no predetermined

folding pattern. Upon inflation, a cross section of a typical balloon would have a substantially rounded outer circumference, as broadly depicted in Fig. 9. Upon deflation, balloons molded with no predetermined folding pattern will flatten out into a "pancake" form, as broadly depicted in Fig. 10. In the past, manufacturers have "wing-folded" deflated balloons such as that shown in Fig. 10 to result in "wing-folded" configuration substantially as illustrated in Fig. 8.

In Fig. 8, E is a portion of the catheter body that forms a lumen which may extend through the balloon to the distal tip of the catheter in order to perfuse various substances. D is the folded balloon. Wing folding is the technique of using digital manipulation or a machine to grab the balloon D above and below the elongated body E and, in effect, fold the balloon into a pair of winglike segments above and below the elongated body E. These two wing segments are folded over the elongated body E as shown in Fig. 8.

In contrast, the balloons of the present invention are molded to have a predetermined folding pattern. The predetermined folding pattern preferably has at least three grooves or depressions 20 which (a) upon inflation, are pressed outward to result in a balloon with a substantially rounded circumference, as depicted in Fig. 9, and (b) upon deflation, pulled inward to result in a collapsed configuration, such as that shown in Fig. 4B, so that the balloon 16 can be twisted and/or more easily and consistently

manipulated into a low profile, folded configuration, such as that shown in Fig. 4A.

In a preferred embodiment, the predetermined folding pattern has four lobes 18 with a groove or depression 20 between each lobe (Figs. 4A, 4B, 5A, 5B). The balloon is molded in a manner that results in "plump" lobes 18 similar to those shown in Figs. 5A and 5B; however, upon deflation, the lobes 18 collapse into a configuration closer to that shown in Fig. 4B. The deflated balloon shown in Fig. 4B can relatively easily be twisted to have the low profile configuration shown in Fig. 4A.

A predetermined folding pattern with four lobes 18 is preferred because it should reduce the widest "diameter" of the deflated, unfolded balloon by about one-half. A deflated balloon with no predetermined folding pattern will assume the "pancake"-like configuration depicted in Fig. 10. The "pancake"-like configuration of a deflated balloon with no predetermined folding pattern has a diameter at its widest point equal to about 4 times the radius of the inflated balloon (x in Fig. 4B). This widest point is indicated in Fig. 10 at line 4x. In contrast, a deflated balloon which has a preferred predetermined folding pattern into four lobes, such as the "lobed" configurations shown in Figs. 4B, 5A, and 5B, has a diameter at its widest point equal to about two times the radius of the inflated balloon (2x in Fig. 4B). When deflated, the maximum diameter of the balloon preferably

should be between about 0.02-0.035 inches, preferably about 0.03 inches.

Persons of ordinary skill in the art will recognize that the predetermined folding pattern could have more than three grooves or depressions, or could have a different configuration--such as a star shape--and still result in a deflated balloon which could be folded into a configuration with a relatively low profile.

The balloon of the present invention may be used with a catheter body 10 having any number of configurations. Preferred configurations are depicted in Figs. 6-7. The body of the catheter 10 depicted in Figs. 6-7 preferably should be between about 135-140 cm long, and approximately 2 cm of this length should be housed within the fitting 14. In a preferred embodiment, the body 10 has a coaxial construction with an outer wall 23 surrounding an outer lumen 24 and an inner wall 21 surrounding an inner lumen 22 (Fig. 6C). A preferred embodiment has a metal wire 26 (Figs. 6-7) disposed in the outer lumen 24 to impart additional stiffness to the catheter body 10. The metal wire 26 preferably is tapered at its distal end for a length of about 10 cm from a normal diameter of about 0.014 inches to a final diameter at its distal end of about 0.005 inches. This taper increases the flexibility and maneuverability of the distal end of the catheter. A preferred material for the metal wire 26 is stainless steel.

In a preferred embodiment, the catheter body 10 preferably consists of extruded tubing made of

polyetheretherketone ("PEEK"), which also adds stiffness to the catheter body 10. Reinforcement may be provided along the first 2.0-2.4 cm of the proximal section 12 as it exits the fitting to provide strain relief. The proximal section 12 of the catheter 10 preferably should have a diameter of between about 3.0-3.5 French. The proximal section 12 preferably has the configuration shown in more detail in Figs. 6-7.

Fig. 6B is a blow-up of the necked down region 30 of the catheter body 10 of Fig. 6A with the lumens 22, 24 and the wire 26 depicted as dotted lines. The smaller diameter, necked down region of the balloon 31 preferably is about 20 cm long. The inner lumen 22 in Fig. 6 also is necked down at regions 28, and the wire 26 is shown disposed in the outer lumen 24. Fig. 6C depicts the inner lumen 22, the outer lumen 24, and the wire 26 in cross section. Figs. 7A-7C depict a preferred embodiment which is substantially the same as that depicted in Figs. 6A-6C, except that the inner lumen 22 is not necked down.

The catheter body 10 can be unitary or formed as multiple components attached by suitable means that are known in the art. For example, the proximal section 12 may be formed as a single unit which may be joined to a separate, smaller diameter unit at the necked down region 30 using known means, such as heat bonding, fusing, or using a biocompatible glue. In a preferred embodiment, the separate, smaller diameter, more distal unit is made of polyethylene.

The balloon 16 has an elongated shape which defines an annular cavity 36 between the balloon 16 and the inner wall 21. The balloon 16 may be sealingly engaged with the catheter body using conventional means. Preferably, the proximal end 32 (Fig. 1) of the balloon 16 should extend about 2 mm proximally over the outer wall 23 at the distal end of the catheter body 10 and the overlapping portions should be heat-fused or bonded by other means. In a preferred embodiment, the outer wall 23 does not extend through the balloon, but ends substantially where the balloon 16 is engaged with the outer wall 23. Preferably, only the inner wall 21 extends through the balloon 16. Preferably, approximately 2-4 mm of the distal ends 34 of the balloon 16 and the inner wall 21 are sealingly engaged using known means, preferably heat-fusing or adhesive bonding.

A guidewire may be inserted through the inner lumen 22 to guide the catheter when it is inserted into a blood vessel or other body cavity. Preferably, the inner lumen 22 should have a diameter that is large enough to permit a suitable guidewire (not shown) to move relatively freely within the lumen 22. The inner lumen 22 also should be large enough to permit active perfusion of blood/fluids with flowrates up to about 100 cc/min. and to permit insertion of a guidewire, but small enough to maintain a low catheter profile. A preferable diameter for the inner lumen is about 0.014 inch. The outer lumen 24 should be as small as possible, but large enough to

retain the metal wire 26 and also permit a sufficient amount of inflation fluid to flow to the balloon 16.

Although the construction of the catheter body 10 is described as substantially "coaxial," it is not necessary for the inner lumen 22 and the outer lumen 24 to have x and y axes that completely coincide. As used herein, the term "substantially coaxial" means that the inner lumen 22 and the outer lumen 24 have x and y axes that are substantially parallel in construction, at least when the catheter is relaxed. During the insertion process, the outer wall 23 may become twisted in relation to the inner wall 21 so that the x and y axes are temporarily dislocated.

In actual manufacture, the catheter assemblies may be stored as two subassemblies until it is known what size of balloon 16 is required. A first subassembly can be the proximal section 12 of the catheter body 10, including the inner wall 21 surrounding the inner lumen 22 that will extend through the balloon 16. A radiopaque marker 38 may be attached to the inner wall 21 at a desired location. Typically, the radiopaque marker should be placed at a location that will be at or near the center of the balloon 16 after final assembly. This first subassembly then may be stored in stock.

Independently, the balloon 16 may be stored in stock as a second subassembly. After it is decided what size of catheter is needed, a correctly sized balloon can be fused to the first subassembly, as already described.

The foregoing disclosure and description of the invention are illustrative and explanatory thereof, and various changes in the size, shape and materials, as well as in the details of the illustrated construction, may be made without departing from the spirit of the invention.

WE CLAIM:

1. A catheter, comprising:
a body comprising a proximal end, a distal end, and at least one lumen therethrough;
a balloon with a predetermined folding pattern comprising at least three collapsible depressions, said balloon being supported by said distal end of said body and sealingly engaged in fluid communication with said lumen.

2. The catheter of claim 1 wherein
said body has at least two lumens therethrough, one of said lumens being a perfusion lumen and another of said lumens being an inflation lumen; and
said balloon is sealingly engaged with said inflation lumen and said perfusion lumen extends through said balloon to a distal end of said catheter.

3. The catheter of claim 1 further comprising a wire disposed within said body to strengthen said catheter.

4. The catheter of claim 3 wherein said wire has a proximal and a distal end and said wire is tapered at said distal end.

5. The catheter of claim 2 further comprising a wire disposed in said inflation lumen.

6. The catheter of claim 5 wherein said wire has a proximal and a distal end and said wire is tapered at said distal end.

7. The catheter of claim 1 wherein said body comprises a portion having a decreased diameter at said distal end.

8. The catheter of claim 7 wherein said decreased diameter portion of said catheter comprises polyethylene.

9. The catheter of claim 3 wherein said body comprises a portion having a decreased diameter at said distal end.

10. The catheter of claim 9 wherein said decreased diameter portion of said catheter comprises polyethylene.

11. The catheter of claim 5 wherein said body comprises a portion having a decreased diameter at said distal end.

12. The catheter of claim 11 wherein said decreased diameter portion of said catheter comprises polyethylene.

13. The catheter of claim 1 wherein said balloon comprises polyvinylidene fluoride.

14. The catheter of claim 1 wherein said body comprises polyetheretherketone.

15. The catheter of claim 13 wherein said body comprises polyetheretherketone.

16. The catheter of claim 3 wherein said balloon comprises polyvinylidene fluoride.

17. The catheter of claim 3 wherein said body comprises polyetheretherketone.

18. The catheter of claim 16 wherein said body comprises polyetheretherketone.

19. The catheter of claim 9 wherein said balloon comprises polyvinylidene fluoride.

20. The catheter of claim 9 wherein said body comprises polyetheretherketone.

21. The catheter of claim 19 wherein said body comprises polyetheretherketone.

22. A device for dilating stenotic lesions in body cavities comprising a body with a lumen therethrough and a balloon sealingly engaged in fluid communication with said lumen wherein said body comprises polyetheretherketone.

23. The device of claim 22 wherein said balloon has a predetermined folding pattern comprising at least three collapsible depressions.

24. The device of claim 23 wherein said balloon comprises polyvinylidene fluoride.

25. A device for dilating stenotic lesions in body cavities comprising a body with a lumen therethrough and a balloon sealingly engaged in fluid communication with said lumen wherein said balloon comprises polyvinylidine fluoride.

26. The device of claim 25 wherein said balloon has a predetermined folding pattern comprising at least three collapsible depressions.

27. A device for dilating stenotic lesions in body cavities comprising a body with a lumen therethrough and a balloon sealingly engaged in fluid communication with said lumen wherein said balloon has a predetermined folding pattern comprising at least three collapsible depressions.

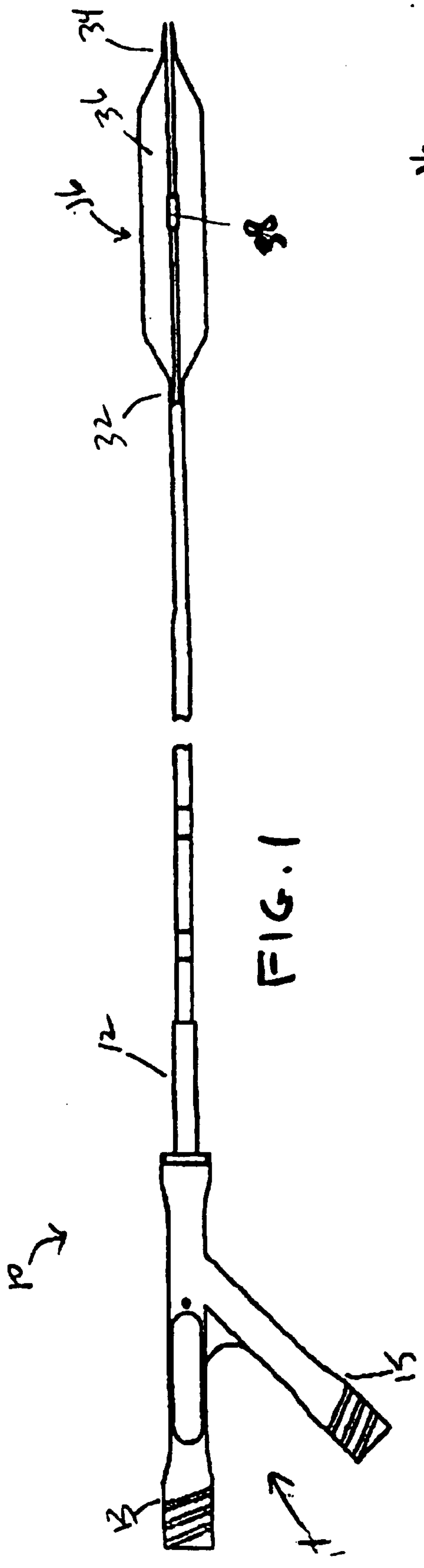

FIG. 1

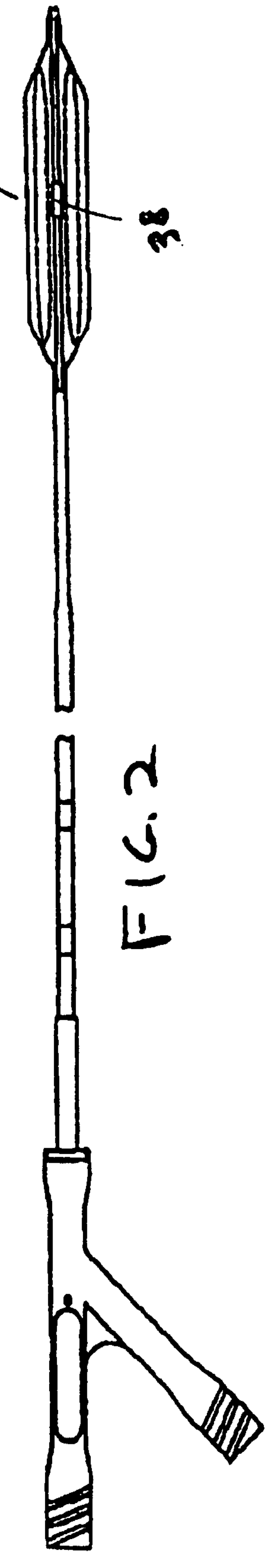

FIG. 2

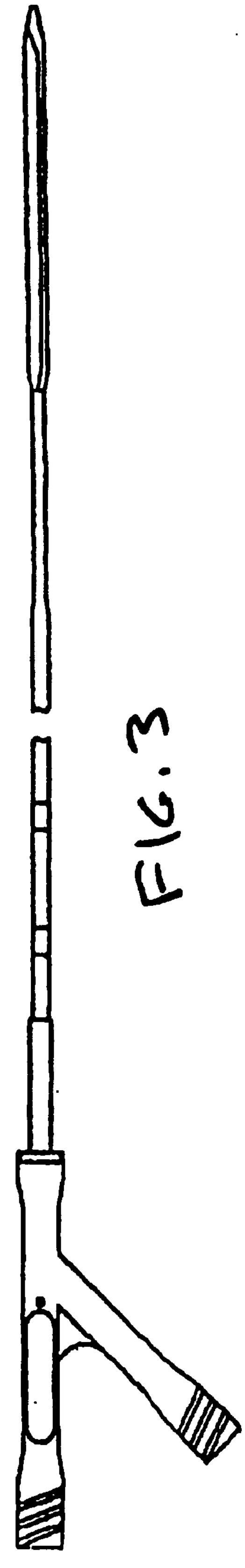

FIG. 3

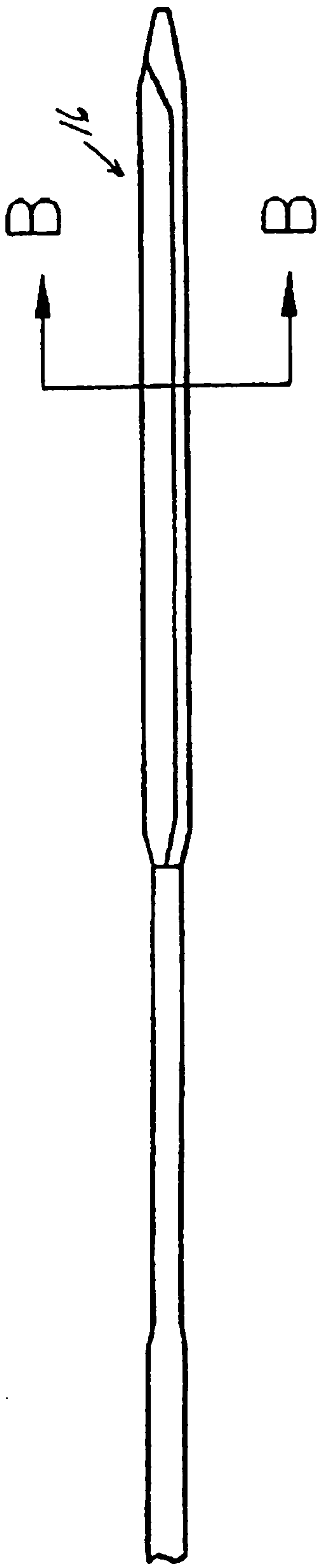

FIG 4

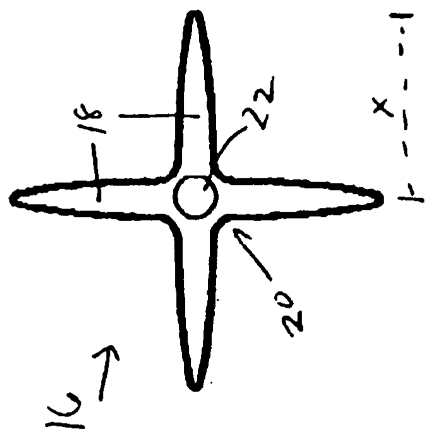

FIG 4B

Section B–B

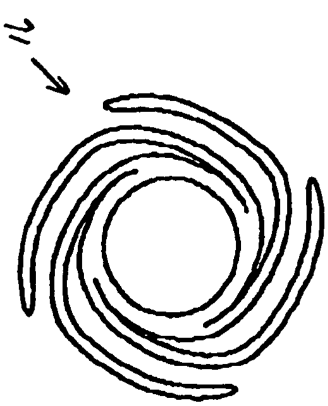

FIG 4A

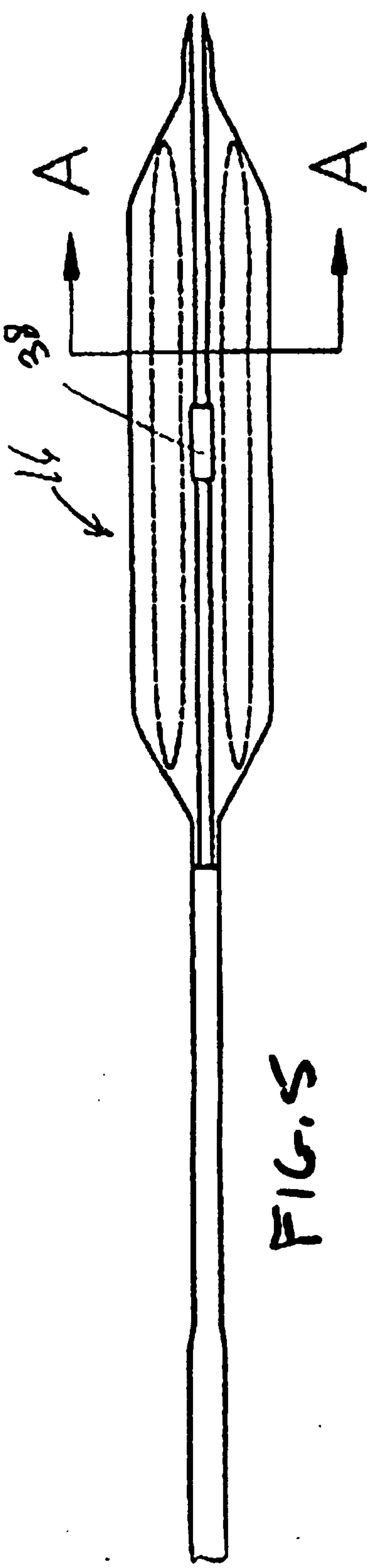

FIG. 5

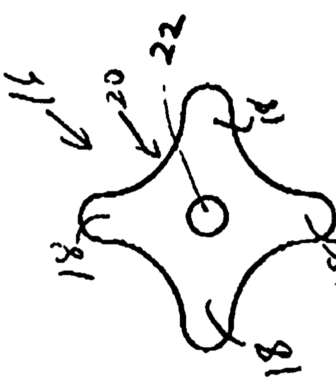

FIG. 5B

Section A—A

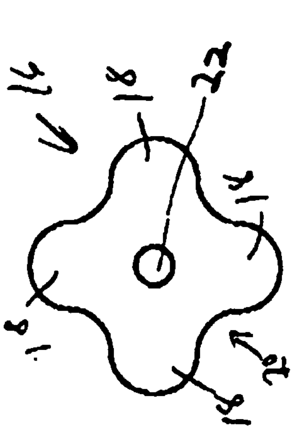

FIG. 5A

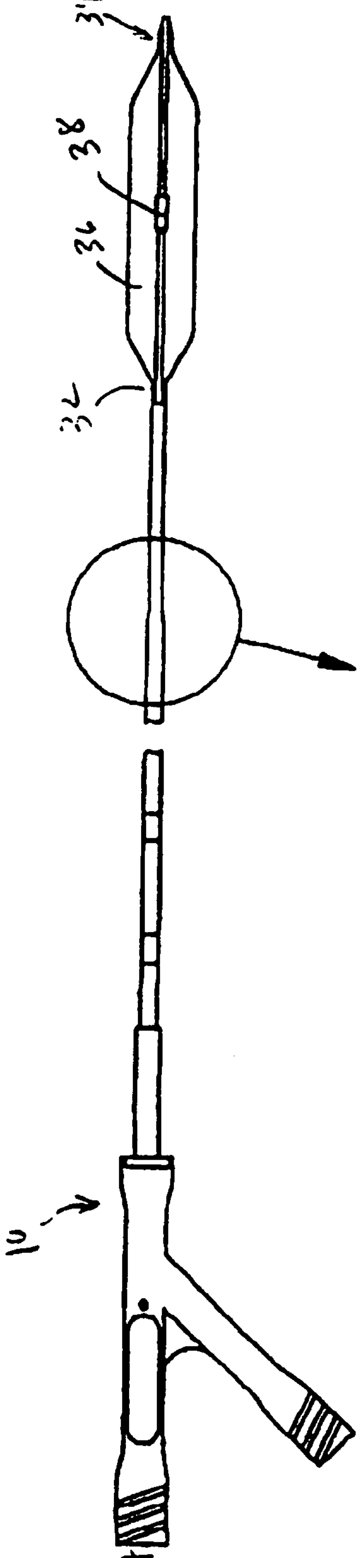

FIG. 6A

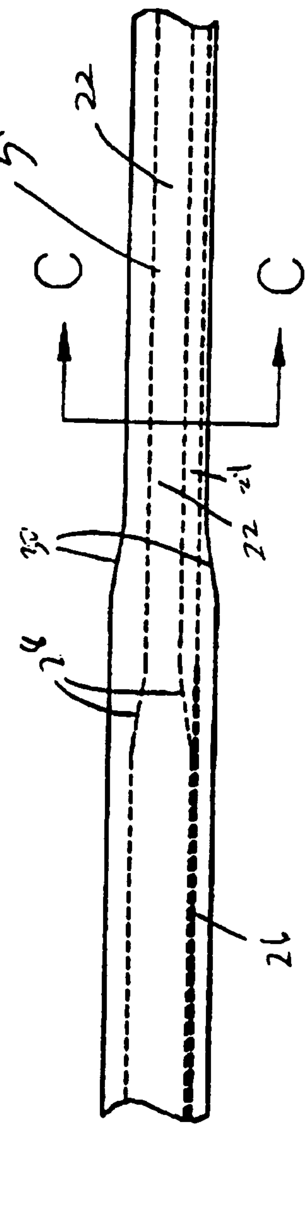

FIG. 6B

Section C—C

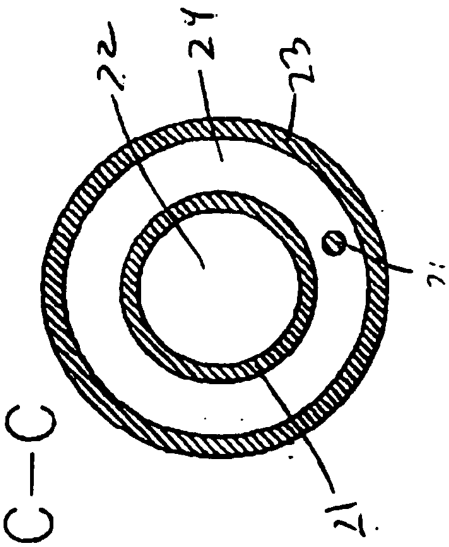

FIG. 6C

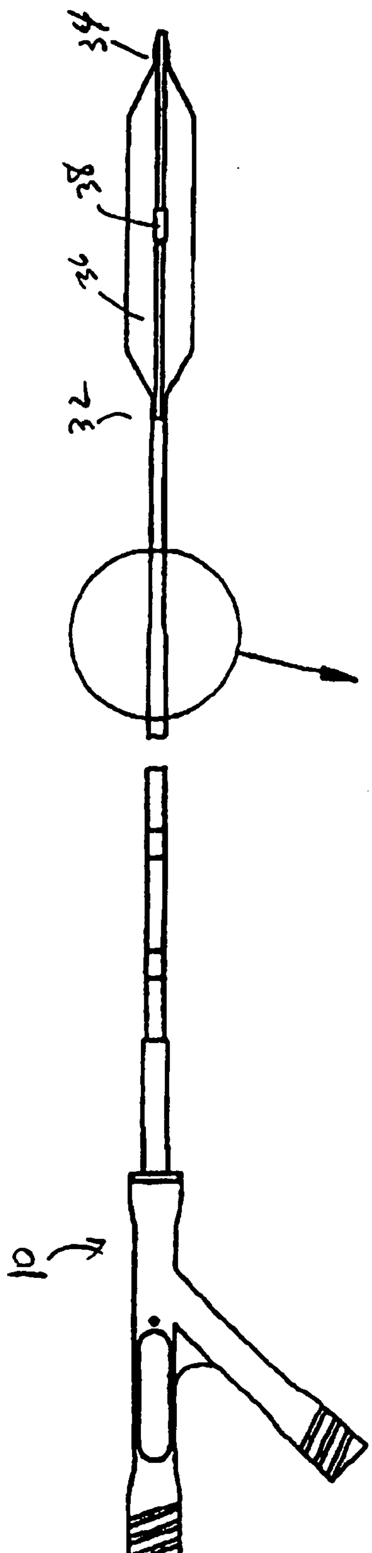

FIG. 7A

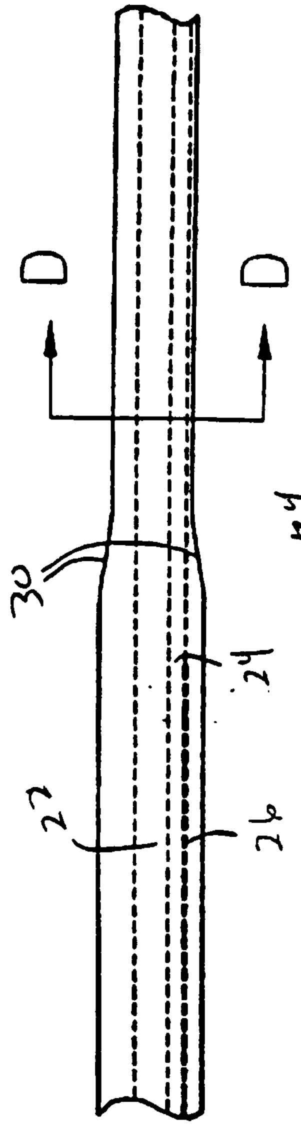

FIG. 7B

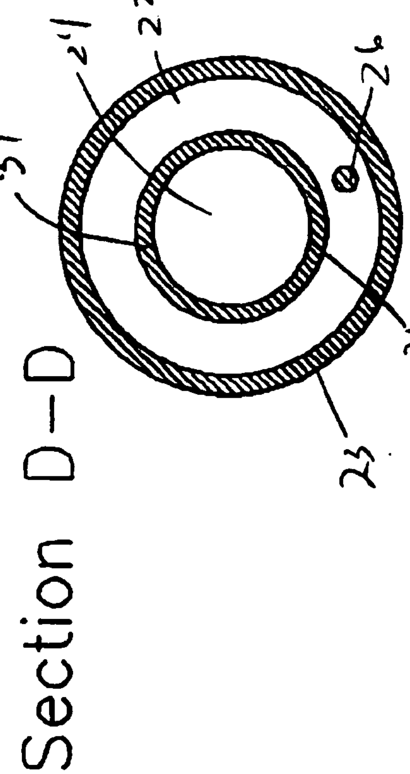

FIG. 7C

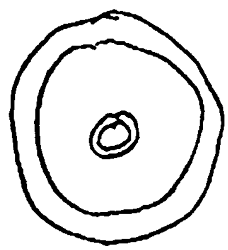

FIG. 9

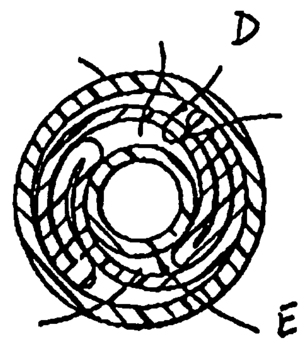

FIG. 8

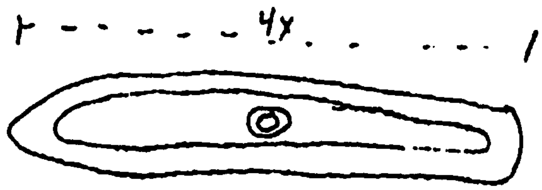

FIG. 10

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US96/20302

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61M 29/00
US CL :604/96; 606/194
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 604/96; 606/194

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

606/191, 192, 198

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

APS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 5,087,246 A (SMITH) 11 February 1992, entire document.	1-27 ---------------- 1-21, 23, 24, 26, 27
X,P ---- Y,P	US 5,554,121 A (AINSWORTH et al) 10 September 1996, entire document.	22 ---------------- 1-3, 7-10, 14, 15, 17-21, 23, 24

[X] Further documents are listed in the continuation of Box C. [ ] See patent family annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
27 MARCH 1997	16 APR 1997

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US96/20302

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X,E ---- Y,E	US 5,609,606 A (O'BOYLE) 11 March 1997. entire document.	25 ---------------- 1, 3, 13, 15, 16, 18, 19, 21, 24
Y	US 5,425,711 A (RESSEMANN et al) 20 June 1995. entire document.	1-6, 11, 12